NOV - 3 2000

K001347

MERIDIAN CO., LTD.

3F., 997-4, Medison Venture Tower, Daechi-Dong, Kangnam-Gu
SEOUL, KOREA
Tel: 82.2.2194.3300 Fax: 82.2.2194.3333

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

APPLICANT'S NAME/ADDRESS:	Meridian Co. Ltd. 3F Medison Venture Tower 997-4 Daechi-Dong Kangnam-Ku Seoul, Korea
CONTACT PERSON:	Hyeon-Seong Myeong
COMMON/USUAL NAME:	Galvanic Skin Response Measurement
CLASSIFICATION NAME:	Galvanic Skin Response Measurement
OWNER/OPERATOR NUMBER:	9038705
CLASSIFICATION:	The Galvanic Skin Response Measurement Device is classified into Class II under 21 Code of Federal Regulation 82.1540.
PERFORMANCE STANDARD:	Meridian Co. Ltd. is not aware of any Special Controls or Performance Standards established for Galvanic Skin Response Measurement Device under Sections 513 and 514, respectively, of the Food and Drug and Cosmetics Act.

SUBSTANTIAL EQUIVALENCE:

Meridian Co. Ltd. believes the Meridian-II and Meridian-Plus are substantially equivalent to the Global Corp's C-29a, and Phazx's VLD-100

Electrical safety of the Meridian systems are achieved by means of reinforced or double insulated parts. Electrical isolation of at least 4000Vac between Applied Part (patient circuit) and Live Part. An isolation transformer isolates the primary line current from the secondary electronics of the system when the AC adapter is connected to the system. The connectors of the probe and other accessories are uniquely designed to prevent accidental connection to an AC power outlet.

The Meridian Systems underdone various electrical safety tests and certify the conformance to the following standards:

1. EN 60601-1 (IEC 601-1), European Norm, Medical Electrical Equipment, including Amendment 1 and 2.

2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

In summary the Meridian-II and Meridian-Plus meet or exceeds all the safety requirements for a medical device in its class. Our dedication to safety is evidenced in the many extra steps we have taken to insure a safe product. Also the Meridian-II and Meridian-Plus has met all the requirements and received a registered CE mark.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Meridian Company, Ltd.
c/o Mr. Andrew Paeng
AP Consulting
P.O. Box 3415
St. Louis, Missouri 63143

Re: K001347
Trade Name: Meridian-II and Meridian-Plus
Regulatory Class: II
Product Code: GZO
Dated: August 3, 2000
Received: August 18, 2000

Dear Mr. Paeng:

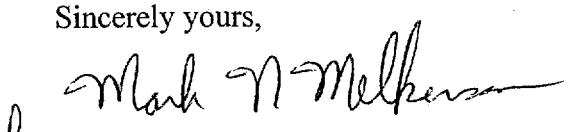
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

PMN 510(k) Number: K001347

Device Name: Meridian-II
Meridian-Plus

Indications for Use:

The Meridian-II and Meridian-Plus, Galvanic Skin Response Measurement Device, is intended use in for the measurement of galvanic skin response.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001347

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 3-10-98)